A how-to manual for newcomers to the field of drug safety, clinical research, regulatory affairs, law and other domains touching on pharmacology who wish to learn the theory and the practicalities of drug safety (pharmacovigilance) and side effects.

This comprehensive and practical guide provides essential information on drug safety and regulations, including recognizing, monitoring, reporting, and cataloging serious adverse drug reactions. Whether you’re working in drug safety, clinical research, regulatory affairs, epidemiology, marketing and sales, nursing, pharmacoepidemiology, or another area in the pharmaceutical industry, FDA (or other regulatory agency), academia, hospital (especially pharmacy or formulary committee) are a lawyer, writer, or other professional who needs to know the details of drug safety and side effects. Training nurses, pharmacists and PharmD and PhD pharmacology students or medical students, this is the book for you! This book teaches the ins and outs of drug safety in the industry, a hospital, FDA, and other health agencies both in the US and around the world, and presents critical information about what is done in the industry and FDA when confronted with a drug safety problem.

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